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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,548	10/14/2003	Jeffrey S. Bauer	6122-66637	3478

24197 7590 06/02/2006

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EXAMINER	
COUNTS, GARY W	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,548	BAUER ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21, 31, 35-38, 40-45, 47 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21, 31, 35-38, 40-45, 47 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/04/06 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-21, 31, 35-38, 40-45, 47 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 the recitation "and analog" there is insufficient antecedent basis for this limitation. Further, it is unclear what analog applicant is referring to. It is also unclear what relationship exists between the analyte, the detectable tracer and the analog.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-5, 10-13, 20, , 21, 31, 35, 36, 40, 41, 45, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al (WO 98/39657).

Boehringer et al disclose a device and method for determining an analyte of interest. Boehringer et al disclose the device comprises a sample receiving zone (sample application area); a labeling zone (mobilization zone); and primary and secondary capture zone (Figure 1). Boehringer et al disclose that the labeling zone can comprise a labeled analyte analog. Boehringer et al disclose that the capture zones comprise an immobilized specific binding pair member. Boehringer et al disclose that

the analyte and labeled analyte analog (tracer molecule) compete for binding to the immobilized binding pair member. Boehringer et al also disclose that the sample flows sequentially past the capture zones (p. 16, lines 9-38). Boehringer et al disclose the flow matrix can be bibulous (p. 31). Boehringer et al disclose that the pore size of the bibulous membrane is 1 to 20 microns (1000 to 20000 nm) (p. 32). Boehringer et al disclose that the sample can be saliva (p. 7). Boehringer et al also disclose that the device and components can be packaged in the form of a kit and that the kit can also contain instructions for performing the methods and interpreting the results (p. 36, lines 1-8).

Boehringer et al differ from the instant invention in failing to specifically state that the detectable tracer molecule migrates through the device at a rate slower than a rate and that the analyte reaches the primary capture area before the tracer reaches the primary capture area.

Although Boehringer et al does not specifically state the slower rate as recited in the claims, Boehringer et al does disclose that the detectable tracer molecule can be a labeled analyte analog (p. 9). Boehringer et al disclose that the analyte analog refers to a modified analyte in which the analyte has been modified to provide a means for attaching the analyte to another molecule. Boehringer et al disclose attaching this analyte analog to BSA coated latex microspheres (p. 43-45). Since the microspheres of Boehringer et al are even larger (0.51u) than the particles disclosed in the specification on page 21 and are coated with BSA, one of ordinary skill in the art would recognize that the rate of migration for the labeled analyte analog would be slower than the rate of

migration of the analyte and thus the analyte would reach the primary capture area before the detectable tracer.

8. Claims 6 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al. in view of Fredrickson (US 6001,658).

See above for teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically teach the detectable tracer is positioned beneath the surface of the test strip on which the liquid sample is placed.

Frederickson teaches detectable tracer impregnated (defined in Webster's as to permeate, permeate is also defined in Webster's as to penetrate or pass through) in a mobilization zone. Therefore, Frederickson teaches that the tracer is beneath the surface of the test strip. Frederickson teaches that this provides for a rapid, volume, timing and temperature independent visually read test strip. Further, the impregnation of labeled reagents within test strips is known in the art as taught by Bogema (US 6,248,598) (col 4, lines 50-56).

It would have been obvious to one of ordinary skill in the art to impregnate the detectable tracer as taught by Frederickson into the device and methods of Boehringer et al because Frederickson teaches that this provides for a rapid, volume, timing and temperature independent visually read test strip. Further, the impregnation of labeled reagents within test strips is known in the art. Therefore, one of ordinary skill in the art would have a reasonable expectation of success impregnating the detectable tracer as taught by Frederickson into the device and methods of Boehringer et al.

9. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Leuvering (US 4,313,734).

See above for teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically state that the detectable tracer comprises a visually detectable label covalently attached to analyte or an analyte analog.

Leuvering disclose particles (detectable tracer) coupled to reactive components. Leuvering disclose that the components can be coupled to the particles by covalent bonds (col 2). Leuvering disclose that these particles carry a charge (col 3) and that the particles can be combined with other reagents. Leuvering disclose that these particles can be visually detected (col 5). Leuvering disclose that the particles can be 100 nm (size which falls within the size disclosed by Applicant on page 21 of the specification). Leuvering disclose that these labels provide for method for the detection and/or determination of one or more components of the reaction between a specific binding protein and the corresponding bindable substance in a test sample (col 1) and also proves to be more sensitive than known techniques (col 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate labels as taught by Leuvering into the device and methods of Boehringer et al because Boehringer et al specifically teaches that labels provided in Leuvering (US 4,313,734) are suitable labels for the device and methods of Boehringer (p. 34, lines 21-37) and also because Leuvering teaches that these labels

provide for method for the detection and/or determination of one or more components of the reaction between a specific binding protein and the corresponding bindable substance in a test sample and also proves to be more sensitive than known techniques. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating the labels of Leuvering into the method and device of Boehringer et al.

With respect to claim 7 since the combination of Boehringer et al and Leuvering disclose the same device and reagents as recited in the instant claims one of ordinary skill in the art would expect the detectable tracer to have a retarded migration rate relative to the migration of the analyte and to also posses a polarity or charge that interacts with the bibulous substrate..

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Leuvering as applied to claims 1-5, 7,10-14, 20, 31, 36, 40, 41 and 45 above, and further in view of Terminiello et al (US 4,774,192).

See above for teachings of Boehringer et al and Leuvering.

Boehringer et al and Leuvering differ from the instant invention in failing to teach the at least one reagent is polyvinyl pyrolidone.

Terminiello et al disclose the treatment of membranes used in the analysis of a fluid sample. Terminiello et al disclose treating the membrane with polyvinyl pyrolidone (PVP). Terminiello et al disclose that the purpose of such conditioning of the membrane provides the advantages of reducing the void space within the matrix of the membrane and to assist or promote the absorption of the fluid fraction of the biological sample.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat the modified device of Boehringer et al with PVP as taught by Terminiello et al because Terminiello et al shows that such conditioning of the membrane provides the advantages of reducing the void space within the matrix of the membrane and to assist or promote the absorption of the fluid fraction of the biological sample.

11. Claims 15, 17-19, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Fitzpatrick et al (US 5,451,504).

See above for the teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically teach the analytes.

Fitzpatrick et al disclose test strips, which will detect any antigen in which the appropriate reagents are used. Fitzpartrick et al disclose that the analyte can be drugs and small analytes of 100 to 1000 Daltons (col 4). Fitzpartrick et al disclose that detecting drugs or drug metabolites affects the choice of proper medical treatment and that the detection of drugs or drug metabolites in a person is also important in law enforcement.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to detect any analyte and incorporate the appropriate reagent such as taught by Fitzpatrick into the test strip and method of Boehringer et al because Fitzpatrick et al shows that the detection of analytes affects the choice of proper medical treatment.

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Hardman et al (US 6,573,108).

See above for teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to specifically teach the detectable tracer comprises a detectable tracer for an analyte comprising an antibody to HIV or Hepatitis.

Hardman et al teach reagents used in test strips for determining an analyte of interest. Hardman et al teaches that antibodies or antigens are used to determine the analyte of interest. Hardman et al teaches the analyte of interest can be HIV or Hepatitis antigens and that one would use antibodies specific for the antigens in testing procedures (col 5, lines 10-37). Hardman et al teaches that this provides for determining for antigens of diagnostic significance.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate reagents such as taught by Hardman et al into the device and methods of Boehringer et al because Boehringer et al specifically teaches the analyte can be a virus (p. 8) and Boehringer et al is generic with respect to the virus and one of ordinary skill in the art would use the appropriate reagents to determine the analyte of interest in the case HIV. Further, Hardman teaches that these reagents provide for determining antigens of interest.

13. Claims 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al in view of Thieme et al (US 5,871,905).

See above for the teachings of Boehringer et al.

Boehringer et al differ from the instant invention in failing to teach the saliva is combined with a bile acid or bile salt.

Thieme et al disclose the use of saliva as a liquid sample in immunoassays involving lateral flow immunochromatographic devices (col 1). Thieme et al disclose that the saliva is combined with a bile salt or acid (col 3, lines 19-25). Thieme et al disclose that the saliva sample combined with the bile acid or salt provides for methods of reducing false positives in assays for the detection of an analyte in an oral fluid sample. Thieme et al also disclose that a chelator such as EDTA can be impregnated into an absorbent pad and that a chelator can be stored within the assay device. Thieme et al disclose that this chelator improves the effectiveness of the bile salt in reducing the incidence of false positives (col 15, lines 42-61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a bile acid or bile salt in combination with the saliva as taught by Thieme et al into the method of Boehringer et al because Thieme et al shows that the saliva sample combined with the bile acid or salt provides for methods of reducing false positives in assays for the detection of an analyte in an oral fluid sample.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a chelator such as taught by Thieme et al into the test strip and method of Boehringer et al because Thieme et al shows that a chelator such as EDTA can be impregnated into an absorbent pad and that a chelator can be stored within the assay device. Thieme et al disclose that this chelator improves the effectiveness of the bile salt in reducing the incidence of false positives.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-4 10-21 31, 35-38, 40-45 and 47 and 49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 18-20 and 25-37 of U.S. Patent No. 6,699,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious that the claims or U.S. Patent No. 6,699,722 would encompass the claims of 1-38 of application 10/686,548.

Response to Arguments

16. Applicant's arguments filed 05/074/06 have been fully considered but they are not persuasive.

Applicant argues that all embodiments of the Boehringer device are designed to perform "non-bibulous" flow and that Boehringer is replete with repeated teaching of "non-bibulous" flow. Applicant directs Examiner's attention to the abstract and to page 24 lines 27-28 that the "matrix is preferably a blocked nitrocellulose capable of non-

bibulous flow". This is not found persuasive because Boehringer et al specifically teaches that the support matrix may be capable of either bibulous or non-bibulous lateral flow (p 31, lines 15-16). Further, it is well settled that a reference must be evaluated for all disclosures not just its preferred embodiments. *In re Mills,* 470 F. 2d 649, 176 USPQ 196 (CCPA 1972). Thus, Boehringer et al disclose the mobilization zone, mobile or moibizalble detactable tracer in the mobilization zone, sample application primary and secondary capture areas, a bibulous substrate and the same reagents as Applicant and also discloses them in the same order as claimed by Applicant. Therefore, Boehringer et al reads on the instantly recited claims. Applicant argues that the Office action incorrectly relies on Boehringer as teaching a disclosure of the same materials in the same order to achieve the same result and directs Examiner's attention to the incorporated references. This is not found persuasive because although Boehringer et al does teach non-bibulous flow and that non-bibulous flow is preferred. Boehringer et al specifically teaches that the support matrix may be bibulous and although Boehringer et al discloses that the bibulous support may be blocked or provide for non-bibulous flow. Boehringer et al does not specifically exclude bibulous flow. In fact, Boehringer et al disclose that it can be bibulous and as stated above a reference must be evaluated for all disclosures not just its preferred embodiments.

Applicants arguments to dependent claims 2-5, 7-9, 31 and 45 are directed toward the arguments that the Boehringer et al reference teaches non-bibulous flow and that Boehringer teaches a blocked methylated-BSA test strip. These arguments are not found persuasive because of reasons stated above that Boehringer et al teaches

bibulous flow and also teaches the same structures and the same reagents as disclosed and recited by applicant and one must consider all disclosures not just the preferred embodiments.

Applicant argues that Fredrickson teaches the tracer is in fact impregnated in a conjugate pad that is layered on top of the membrane along which the applied sample migrates and that this is the opposite of the structure the structure of claim 6 wherein the tracer is beneath the surface of the test strip. This is not found persuasive because the Examiner has not relied upon using the reagents or conjugate pad of Fredrickson as it appears to be suggested by Applicant, but rather the Examiner merely depends on Frederickson for teaching that it is known within the art to impregnate a substrate with reagents. Therefore, it would have been obvious to one of ordinary skill in the art to impregnate the detectable tracer of Boehringer et al as taught by Frederickson. Further as stated above and as evidenced by Bogema (US 6,248,598) (col 4, lines 50-56) the impregnation of test strips with reagents is known within the art and well within the realm of one of ordinary skill in the art.

Applicant argues that a terminal disclaimer was filed in the case on December 2, 2005 and that the obviousness type double patenting rejection has therefore been obviated. This is not found persuasive because as stated in the Advisory Action filed 10/18/05. The terminal disclaimer was found persuasive for only claims 5-9 and that the remaining claims are still rejected under obviousness-type double patenting because claim 1 is broader than the claims of '722 patent which requires the tracer have a weight

greater than the analyte. And one of ordinary skill in the art would recognize that the more narrow claims of '722 would encompass the broader claims listed above.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
May 16, 2006

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